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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/750,293	12/31/2003	Sangeeta N. Bhatia	1034123-000095	9194
41790 7590 12/12/2007 BUCHANAN, INGERSOLL & ROONEY LLP P.O. BOX 1404 ALEXANDRIA, VA 22313-1404			EXAMINER KUHN, ALLAN R	
			ART UNIT 1791	PAPER NUMBER
			NOTIFICATION DATE 12/12/2007	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/750,293	Applicant(s) BHATIA ET AL.	
	Examiner Allan Kuhns	Art Unit 1791	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30,31,34-46 and 48-64 is/are pending in the application.
- 4a) Of the above claim(s) 39-44 and 54-59 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 30,31,34-38,45,46,48-53 and 60-64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>092707</u> . | 6) <input type="checkbox"/> Other: _____ |

1.Claim 48 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This claim is indefinite since it depends from canceled claim 23.

2.The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3.Claims 30, 34-38, 45, 46, 49 and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ma (6,872,387) as set forth in the previous Office action in view of EP 1 027 897 (Mahmood et al.) While Ma appears not to teach an assembly of two or more polymer scaffolds to provide a layered polymer scaffold, Mahmood et al. teach this aspect, in an alternative embodiment, at column 6, lines 42-49 (note that in this alternative embodiment, a second layer which may be a polymer layer coated with a ceramic layer may be combined with the first polymer layer). It would have been obvious to one of ordinary skill in the art to incorporate this teaching of Mahmood et al. into the scaffold structure of Ma in order to produce engineered tissue.

4.Claims 31, 50-53 and 60-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 1 027 897 (Mahmood et al.). Mahmood et al. disclose or suggest a microfabricated (note that it is disclosed in the Example at column 8, line 5 that a porous material only 300 microns thick is formed) polymer scaffold. While Mahmood et al. appear not to state that the article formed is a membrane, it is disclosed in paragraph

[0009] at column 2, lines 23-28 that the scaffold will allow diffusion through the material itself as well as through its porous structure. Given this disclosure, it would have been obvious to one of ordinary skill in the art to recognize that the structure of Mahmood et al. is capable of functioning as a membrane based on these physical properties described. It is submitted that the structure of Mahmood et al. inherently has a varied or varying topology when viewed at a microscopic level.

The structure of Mahmood et al. is porous, as in claim 60, which can be mesh-like, as in claim 61, depending on the size of the pores. Mahmood et al. teach a plurality of such structures, as in claim 62, for example in the embodiment disclosed at column 6, lines 42-49, and the attachment of cells, as in claim 63, at column 2, lines 27-29. Mahmood et al. disclose a scaffold formed of a biopolymer (column 2, lines 37-39), as in claim 50, the formation of a hydrogel (column 2, line 24), as in claim 52, and the use of a polyethylene glycol (column 3, lines 30-42), as in claim 53. At least one of the materials of claim 51 is a well known scaffold forming material, and its use would have been obvious to one of ordinary skill in the art in order to incorporate specific physical properties of that polymer into the scaffold.

5.Applicants' arguments filed September 28, 2007 have been fully considered but they are not persuasive. Applicants' arguments are considered to be moot by the examiner based on the revised grounds of rejection set forth in this Office action.

6.Any inquiry concerning this communication or earlier communications from the examiner should be directed to Allan Kuhns whose telephone number is (571) 272-

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1202. The examiner can normally be reached on Monday to Thursday from 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Johnson, can be reached on (571) 272-1176. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Allan R. Kuhns
ALLAN R. KUHN
PRIMARY EXAMINER AU 1791